UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

CORBIN THOMPSON; Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; BAYER AG; BAYER PHARMA AG; and MERCK & CO., INC.; Defendants.	Case No.: _____ **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL** **1. Strict Liability** **2. Product Liability – Failure to Warn** **3. Negligence** **4. Breach of Express Warranty** **5. Breach of Implied Warranty** **6. Fraud** **7. Negligent Representation** **8. Fraudulent Concealment**

COMPLAINT FOR DAMAGES

Plaintiff, by and through counsel, file this Complaint for damages against Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Corporation, Bayer AG, Bayer Pharma AG, Merck & Co., Inc. (collectively referred to as "Defendants" or "Bayer Defendants"), as follows:

INTRODUCTION

1. This case involves the prescription drug Avelox® (moxifloxacin) (referred to hereafter as "Avelox" or "FLQs").

2. Avelox is designed, developed, manufactured, tested, packaged, promoted, marketed, advertised, distributed, labeled, and/or sold by the Bayer Defendants.

3. The Bayer Defendants are referred to herein as "Defendants."

4. Plaintiff maintains that Avelox is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce to treat infections for which it was not required, and lacked proper warnings and directions as to the dangers associated with its uses.

PARTIES

5. Plaintiff is an individual who at all relevant times was a resident and citizen of Multnomah County, Oregon and bring claims for personal and economic injuries sustained by the use of the Defendants' FLQ drug Avelox. By reason of the foregoing acts and omissions and as a direct and proximate result of being prescribed and ingesting Defendants' FLQs, Plaintiffs sustained personal injuries, including irreversible peripheral neuropathy which is lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, physical impairment, expenses for hospitalization and medical treatment, and loss of earnings, among other damages.

6. Defendant Bayer HealthCare Pharmaceuticals, Inc. ("Bayer Healthcare") is a Delaware corporation that has its principal place of business at 100 Bayer Boulevard, in Whippany, New Jersey 07981.

7. In January 2008, Bayer Pharmaceuticals Corporation was merged into Bayer Healthcare.

8. Bayer Healthcare is involved in the labeling, supplying, selling, and distribution of pharmaceutical products, including Avelox, in the United States.

9. Defendant Bayer Corporation ("Bayer Corp.") is an Indiana corporation that has its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

10. Bayer Corp. (formerly known as Miles, Inc.) is an American subsidiary of a German parent, Bayer AG.

11. Bayer Corp. was engaged in the business of testing, manufacturing, distributing, marketing, advertising, labeling, and selling Avelox in the United States.

12. Bayer AG ("Bayer AG") is a pharmaceutical company domiciled in Germany.

13. Bayer AG is one of the largest pharmaceutical companies in the world and is the researcher, developer, producer, and/or manufacturer of Avelox.

14. Bayer Pharma AG ("Bayer Pharma AG") is a pharmaceutical company domiciled in Germany.

15. Bayer Pharma AG is formerly known as Bayer Schering Pharma AG and is the

same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG was formerly known as Schering AG and is the same corporate entity as Schering AG.

16. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

17. Upon information and belief, Bayer Schering Pharma AG was renamed Bayer Pharma AG effective July 1, 2011.

18. Bayer Pharma AG is involved in the research, development, manufacturer, sale, and/or marketing of pharmaceutical products, including Avelox.

19. Upon information and belief, and at all relevant times, Defendant Bayer Pharma AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Avelox.

20. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation that has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

21. Merck has promoted Avelox in the United States since its acquisition of Schering-Plough Corporation on November 4, 2009.

22. At all times material hereto, Merck was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avelox.

23. Defendants are authorized to do business in this district and derive income from doing business in this district.

24. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities within this district, thus invoking the benefits and protections of its laws.

25. Upon information and belief, the Bayer Defendants did act together to design, sell, advertise, manufacture and/or distribute Avelox with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

26. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiffs and Defendants.

27. Defendants have significant contacts in the vicinage of this district such that they are subject to the personal jurisdiction of the court in this district.

28. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in this district. Pursuant to 28 U.S.C. § 1391(a), venue is proper in both districts.

FACTUAL ALLEGATIONS

29. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the FLQ drug Avelox.

30. Plaintiff Corbin Thompson was prescribed and/or otherwise lawfully obtained Avelox on or about January 2011. Thereafter, Plaintiff began suffering symptoms of peripheral neuropathy. Plaintiff was subsequently diagnosed with peripheral neuropathy.

31. FLQs are broad-spectrum synthetic antibacterial agents marketed and sold in oral tablet, IV solution, and ophthalmic solution, used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria. They are members of the quinolone class of antibiotics.

32. Quinolones are divided into four generations based on their spectrum of antimicrobial activity. The 1st generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

33. Twenty years later, in the early 1980s, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called 2nd generation quinolones included Noroxin® (norfloxacin), Cipro, Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the

United States).

34. Cipro was approved by the United States Food and Drug Administration ("FDA") in October 1987 for use in the United States, and is the brand name for the antibiotic ciprofloxacin. Since its introduction to the market in the United States in 1987, the Bayer Defendants have derived over $1 billion in U.S. net sales of all Cipro products. Cipro went off patent on December 9, 2003.

35. Fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the United States market due to unacceptable risks of certain adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

36. Avelox was approved by the FDA on December 10, 1999 for use in the United States, and is the brand name for the antibiotic moxifloxacin.

37. With the patent for Cipro (another blockbuster fluoroquinolone) set to expire in December 2003, the Bayer Defendants set out to develop and effectively market Avelox in order to be more competitive with 3rd and 4th generation fluoroquinolones, including Levaquin. Avelox quickly became the Bayer Defendants' heir apparent and successor to Cipro.

38. Similar to Cipro, Avelox has proven to be a blockbuster drug for the Bayer Defendants. In 2007 alone, Avelox generated international sales of $697.3 million dollars.

39. Defendant Bayer Healthcare has indicated on its website that Avelox is "safe and effective" and "has a well-characterized safety profile, which has been studied in over 14,000 patients in clinical trials and 92,000 patients in post marketing surveillance studies."

40. However, the scientific evidence has established a clear association between Avelox and an increased risk of long-term and sometimes irreversible peripheral neuropathy.

41. Prior to applying to the FDA for and obtaining approval of Avelox, Defendants knew or should have known that consumption of Avelox was associated with and/or would cause chronic and/or permanent peripheral neuropathy.

42. By 1988, Defendants possessed at least one published case report (funded in part by Bayer),[1] which Defendants knew or should have known constituted a safety "signal" that the use of FLQs was associated with "peripheral paraesthesia" (a form of peripheral nerve damage) and required further investigation and study.

43. Defendants failed to appropriately and adequately inform and warn Plaintiff and Plaintiff's prescribing physicians of the serious and dangerous risks associated with the use of FLQs concerning irreversible peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, physical impairment, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

44. The warning label for Avelox from September 2004 through July 2012 misled and deceived Plaintiff and Plaintiff's treating physicians by incorrectly advising them that peripheral neuropathy associated with FLQs was "rare." The Avelox label during this time period also omitted any mention of the possibility that FLQ use could result in irreversible peripheral neuropathy.

45. Further, though this injury can be severe and debilitating, the language regarding the "rare" risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Defendants' FLQ labels; the language was in no way highlighted for the benefit of prescribing physicians and patients.

46. Additionally, upon information and belief, following the 2004 label change

[1] *See* Therapy of acute and chronic gram-negative osteomyelitis with ciprofloxacin. Report from a Swedish Study Group (Karlman, K. et al.). *J Antimicrob Chemother* 1988 Aug;22(2):221-8.

Defendants did not issue any "Dear Doctor" or "Dear Healthcare Professional" letters in the United States that were specific to Avelox and the risk of developing irreversible peripheral neuropathy. Further, Defendants failed to disclose the serious and dangerous side effect of irreversible peripheral neuropathy when promoting Avelox to physicians.

47. Despite their knowledge that their FLQ drugs were associated with an elevated risk of prolonged and/or permanent peripheral neuropathy, Defendants' promotional campaign was focused on the purported "safety profile" of their FLQs.

48. FDA regulations require that manufacturers monitor and report adverse events ("AEs") associated with their marketed products. 21 C.F.R. § 314.80; 21 C.F.R. § 314.81. The manufacturers are required to review all adverse experience information pertaining to their products obtained from any source, foreign or domestic, including from commercial marketing experience, postmarketing clinical investigations, post-marketing epidemiological/surveillance studies, reports in the scientific literature and unpublished scientific papers. Manufacturers review this information for safety "signals."

49. The FDA has recognized that case reports and case series can play important roles in serving as "safety signals." In fact, the FDA states that a single, well-documented case report can be viewed as a safety signal, particularly if the report describes a positive rechallenge.[2]

50. Indeed, even a single case report may be sufficient to establish a *causal* relationship between the use of a product and an adverse event.[3]

51. In the pharmaceutical industry, including within Defendants' companies, safety signals generally indicate the need for further investigation.[4]

52. After a signal is identified, the Bayer Defendants are obligated to further assess

---

[2] *See* U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Good Pharmacovigilence Practices and Pharmacoepidemiologic Assessment (2005).

[3] *See* Principles & Practice of Public Health Surveillance, at p. 343. Steven M. Teutsch & R. Elliott Churchill, eds. Third Edition, Oxford University Press, 2010.

[4] *See* Guidance for Industry: Good Pharmacovigilence Practices and Pharmacoepidemiologic Assessment (2005).

the signal to determine whether it represents a potential safety risk that should be included in product labeling.

53. The Bayer Defendants claim that "[w]e maintain accurate product labels that share information about the benefits and risks associated with fluoroquinolone use, and report all adverse events we learn about to the FDA."[5]

54. Despite these representations, as early as 1988 there was evidence in the medical literature of peripheral nerve damage associated with FLQ therapy (ciprofloxacin), representing a safety "signal" that the Bayer Defendants ignored in violation of the federal regulations.[6] Specifically, in a report from a Swedish Study Group, funded in part by Bayer, Karlman et al. reviewed 40 patients treated with ciprofloxacin for acute or chronic osteomyelitis (38) and acute arthritis (2). The authors identified 9 patients with adverse experiences. Of these 9 adverse experiences, the authors reported one case of "peripheral paraesthesia" which they found was "probably related" to ciprofloxacin treatment.[7]

55. Thereafter, a 1990 study by Chan et al. reviewed 27 patients treated with the fluoroquinolone Peflox for urinary tract infections.[8] One patient developed peripheral neuropathy that resolved 4 weeks after discontinuation, generating an incidence rate of 3.7%. The authors concluded that "[i]ts [i.e. peripheral neuropathy's] relation to the use of pefloxacin was *indisputable*, since it recurred on re-introduction of the drug." (emphasis added). Reviewers at the FDA's Office of Surveillance and Epidemiology (OSE) concluded in an April 17, 2013 pharmacovigilence review that this case represents a positive dechallenge.

56. Then, in 1992, Aoun et al. published a case report titled "Peripheral neuropathy

---

[5] https://www.washingtonpost.com/national/health-science/it-pays-to-read-the-warnings-when-you-open-up-a-prescription/2015/08/03/a29e11b4-d70e-11e4-b3f2-607bd612aeac_story.html.
[6] *See* 21 C.F.R. 201.57(e) (product label must be revised as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved).
[7] *See* Karlman, K. et al. (Report from a Swedish Study Group). Therapy of acute and chronic gram-negative osteomyelitis with ciprofloxacin. *J Antimicrob Chemother* 1988 Aug;22(2):221-8.
[8] Chan, PC et al., Clinical experience with pefloxacin in patient with urinary tract infections, *Br. J. Clin. Pract.* 1990.

associated with fluoroquinolones."[9] Specifically, the authors reported an association between the use of pefloxacin, ofloxacin and ciprofloxacin and peripheral neuropathy in a 37 year old patient. The case report was notable for numerous positive dechallenges and rechallenges of the fluoroquinolones in the patient, resulting in reviewers at FDA's OSE to characterize the quality of the evidence reported as a "strong case."

57. In 1996, Hedenmalm et al. reported the results from a review of 37 patients treated with fluoroquinolones.[10] Of those, 81% experienced paresthesia, 51% experienced numbness, 27% experienced pain, and 11% experienced muscle weakness. The highest incidence of reported symptoms occurred during the first weeks of treatment. The duration of symptoms in the cases where information was provided varied from a few hours to over a year. According to reviewers at FDA's OSE, the quality of evidence from at least 20 of the 37 cases seemed to be "strong with both a good temporal relationship and a positive dechallenge."

58. One of the first large scale studies in the United States that included the post market experience concerning fluoroquinolones and neuropathy was "Peripheral Neuropathy Associated with Fluoroquinolones" written by Jay S. Cohen. The Cohen paper was published in December 2001 and revealed that adverse events reported by 45 patients suggested a possible association between fluoroquinolones and long-term peripheral nervous system damage. The study noted in particular the presence of severe and/or persistent nerve problems. Over one-half of the patients surveyed said their symptoms lasted for more than a year, and eighty percent characterized their symptoms as severe. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy. The study concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for

---

[9] Auon, M. et al. Peripheral neuropathy associated with fluoroquinolones. Letter to Editor. *Lancet*. 1992.

[10] Hedenmalm, K. et al. Peripheral sensory disturbances related to treatment of fluoroquinolones. *J. Antimicrob. Chemother*. 1996;37:831-7.

these drugs' product information."

59. Beyond the numerous safety signals generated by internal postmarketing review and the medical literature, Defendants were also put on notice of an association between fluoroquinolone use and peripheral neuropathy by the FDA, in 2001 and again in 2003.

60. In 2001, the Division of Drug Risk Evaluation within the Office of Drug Safety uncovered 35 reports of quinolone-associated peripheral neuropathy and 46 cases of potentially prolonged paresthesia collected by the FDA's Adverse Event Reporting System ("AERS") for the quinolone class (including reports for ciprofloxacin, ofloxacin, and levofloxacin). Twenty-eight of these cases lasted over one month, with some patients still experiencing symptoms two years after fluoroquinolone use.

61. In 2003, FDA's Office of Drug Safety conducted an additional post-marketing safety review of the AEs reported in the FDA's AERS for those who had been treated with ciprofloxacin (Cipro), ofloxacin (Floxin), and/or levofloxacin (Levaquin). The AERS contained 108 unduplicated cases reported as peripheral neuropathy, or events suggestive of peripheral neuropathy, lasting at least one month in patients who had been treated with ciprofloxacin, ofloxacin and/or levofloxacin. As noted in the FDA's Office of Drug Safety review report dated June 10, 2003, the cases were temporally associated with fluoroquinolones, with a median time to onset of a few days. Gender distribution was approximately equal. The report further stated that these cases provided an indication that the fluoroquinolones could have been responsible for the prolonged peripheral neuropathies. As a result of its review, the Office of Drug Safety recommended that "peripheral neuropathy" be added to the labeling for ciprofloxacin and levofloxacin as it had been for ofloxacin.

62. In September 2004, Defendants amended the labeling for Avelox. The amended label contained the following statement in the Warnings section:

> **Peripheral Neuropathy**: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones.

63. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that Defendants' existing warnings regarding peripheral neuropathy were inadequate. On August 15, 2013, an updated warning and accompanying safety communication was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included in the labels for all fluoroquinolones, including Avelox. The updated warning also removed the statement that peripheral neuropathy occurred only in "rare" cases:

> Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including [drug name]. Symptoms may occur soon after initiation of [drug name] and may be irreversible. [Drug name] should be discontinued immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.

64. Additionally, Defendants' updated label does not disclose the serious, progressive and disabling nature of FLQ-induced irreversible peripheral neuropathy.

65. Upon information and belief, Defendants failed to provide adequate information to the medical community about the frequency with which AEs indicative of peripheral neuropathy were being reported. Prior to the August 2013 label change, Defendants knew or should have known that FLQ-associated neuropathies could be rapid, permanent, and disabling, and that such injuries were not, as they had been stating, "rare." For instance, from September 2004 through August 2013, the FLQ labels stated that "Rare cases of polyneuropathy affecting small and/or large axons resulting in *paresthesias*, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones" (emphasis added). The pre-2013 Avelox label further represented that "the most common adverse drug reactions (≥3%) are nausea, diarrhea, headache, and dizziness."

66. Even though the Bayer Defendants represented, through their labeling, to patients and the medical community that central nervous system AEs such as *paresthesias* were "rare"

and were not a common adverse drug reaction, Defendants knew the opposite to be true.[11]

67. Defendants' failure to adequately warn physicians resulted in: (1) patients receiving FLQs instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which patients presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with FLQs.

68. The failure of Defendants to include appropriate warnings in their products' labels as published to the medical community also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

69. Despite Defendants' knowledge and failure to adequately warn Plaintiff and physicians of the above, Defendants continued to market Avelox as a first-line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections—conditions for which many safer antibiotics were and are available.

70. In January of 2014, Ayad Ali published "Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis," which reemphasized the link between fluoroquinolones and peripheral neuropathy and called for increased scrutiny of the risk-benefit of fluoroquinolone prescriptions.

71. An epidemiologic study published in the August 2014 online edition of *Neurology* provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.[12] The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a statistically significant higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI:

[11] "Paraesthesia" is an abnormal sensation, typically tingling or prickling ("pins and needles"), burning, or numbness, caused primarily by damage to peripheral nerves.

[12] Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. *Neurology* 2014; Epub 2014 Aug 22.

1.49-2.27), with current users having the highest risk of exposure (RR = 2.07, 95% CI: 1:56-2.74).

72. On November 5, 2015, the FDA held a joint meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss the safety and efficacy of systemic fluoroquinolones in the context of three indications: acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis in those with chronic obstructive pulmonary disease (ABECB-COPD), and uncomplicated urinary tract infections (uUTI). The FDA asked committee members to determine whether the benefits of FLQ therapy in these three indications justifies the associated risks of FLQ use.

73. While fluoroquinolones are currently approved for these three indications, FDA reviewers, along with over 30 open public hearing speakers, voiced the need for stronger labels on these indications due to the modest or absent treatment benefits of the drugs for the three indications, and the serious adverse events associated with their use. These serious adverse events include tendonitis, tendon rupture, central nervous system effects, peripheral neuropathy, myasthenia gravis exacerbation, phototoxicity, hypersensitivity and certain cardiovascular effects (i.e., QT prolongation).

74. In advance of the advisory committee meeting, FDA reviewers released briefing documents that indicated the potential side effects of fluoroquinolone use, including permanent peripheral neuropathy, may outweigh the benefits provided by the medications, as patients often receive the drugs for infections that resolve themselves or can be treated with medications that do not carry the same risks. For instance, an evaluation of placebo-controlled trials in ABS or mild ABECB-COPD showed that a large proportion of patients randomized to receive placebo recovered and thus the illnesses appeared to be self-limited for many. Moreover, some trials failed to show any differences in outcome measures when comparing the antibacterial drug to placebo.

75. A lengthy review of serious and sometimes permanent adverse events, including permanent peripheral neuropathy, associated with FLQ use followed the discussion of

questionable efficacy for the three indications in question. The FDA cited specifically adverse event reporting from patients highlighting a "constellation of symptoms" referred to as "Fluoroquinolone-Associated Disability" (FQAD). Individuals with FQAD were defined by the FDA as patients who were prescribed an oral fluoroquinolone to treat urinary tract infections, bronchitis or sinusitis, and who experienced disabling adverse events, lasting 30 days or longer, in two of the following body systems: neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, cardiovascular.

76. After hearing testimony from industry representatives, as well as dozens of individuals who described a wide range of harmful effects on their health and cognitive ability from fluoroquinolone use, the panel voted overwhelmingly that the benefits and risks for systemic fluoroquinolone drugs do not support the current labeled indications for the treatment of ABS (unanimous), ABECB-COPD (18-2, with one abstention), or uncomplicated urinary tract infection (20-1).

77. On May 12, 2016, the FDA issued a safety announcement advising that "the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options." The FDA instructed that patients with these conditions should not be treated with a fluoroquinolone if alternative treatment options are available. The May 12th announcement also cautioned that a safety review demonstrated that FLQs "are associated with disabling and potentially permanent serious side effects that can occur together." The side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

78. Upon information and belief, on or around May 12, 2016, the FDA issued a safety labeling change notification to the Bayer Defendants. Among other things, the notification directed Defendants to update their FLQ labels to provide new safety information regarding "serious adverse reactions [that] can occur together and can be disabling and potentially irreversible." The FDA also required a revision to the boxed warning for FLQs to include new warnings regarding peripheral neuropathy and central nervouse systems effets.

79. Notably, the Bayer Defendants have publicly acknowledged that FLQs can cause neuropathy. At the FDA's joint advisory committee meeting in November 2015, Dr. Susan Nicholson, Vice-President of safety, surveillance, and risk management for the Johnson & Johnson Family of Companies, testified on behalf of Janssen Pharma and the other industry partners, including the Bayer Defendants.[13] Dr. Nicholson was asked the following question by the FDA subcommittee concerning quinolones and their causal relationship to tendon ruptures, severe arrhythmia, *and neuropathy*:

> Q: Dr. Winterstein [FDA]: So for the tendon piece, I think there is a fairly good body of literature now that looks at collagen tissue. And to me, that seems to be also a plausible mechanism for neuropathy. So I guess my question is, number one, when does it have to be a unified mechanism or what exactly did that refer to? And then number two, *does the sponsor disagree*, number one, that quinolones cause tendon ruptures, that quinolones cause severe arrhythmia, and then number three, *that quinolones cause neuropathy*? . . . So I'm just trying to get my arms around what the issue is here. *But it seems like we agree that there is a causal association with these three outcomes that we are discussing. Yes*?
>
> A: Dr. Nicholson: *Yes. We do agree.*

APPLICATION OF THE STATUTE OF LIMITATIONS

80. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

81. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Defendants' FLQ drugs, including the actual incidence of FLQ-induced peripheral neuropathy, the serious, progressive and disabling nature of FLQ-induced peripheral neuropathy, the rapid

[13] As noted at the meeting by Melissa Tokosh, global regulatory leader with Janssen Research and Development, "Our participation [at this hearing] represents a collaborative effort between both branded and generic companies, with Bayer and Janssen leading the preparation of the background documents and presentation based on data from our products."

onset of FLQ-induced peripheral neuropathy, and the irreversibility of FLQ-induced peripheral neuropathy.

82. The time, place and substance of the Defendants' alleged fraud is set forth as follows. Between 1995 and 2002, FLQs became the most commonly prescribed class of antibiotics to adults in the United States.[14] The explosive increase in FLQ prescriptions was a direct result of Defendants' deliberate decision to reframe FLQs from a "big gun" antibiotic that should be reserved for serious infections to a "first choice" antibacterial that is appropriate for a wide range of mild infections.

83. One key obstacle to Defendants' re-branding scheme was their awareness of the nature and extent of peripheral neuropathy that could result from taking FLQs. Defendants had long been on notice that FLQs were associated with serious nerve injuries. For example, paraesthesia (or paresthesia) is a medical term that refers to a burning or prickling sensation that is usually felt in the hands, arms, legs, or feet. Paresthesia is considered a hallmark of peripheral neuropathy but is believed to be more commonly reported in clinical trials and adverse event reports due to the lack of an immediate confirmation of the diagnosis of neuropathy. Indeed, since 2004 Defendants have admitted in their Avelox labeling that FLQ-associated peripheral neuropathy results in "paresthesias, hypoesthesias, dysesthesias and weakness." Thus, reports of paresthesia, hypoesthesia, dysesthesia and weakness are consistent with a person who is suffering from peripheral neuropathy, even though that person may not yet have been formally diagnosed.

84. For more than a decade, Defendants have known that paresthesia and other symptoms associated with peripheral neuropathy were among the most common side effects of FLQs.

85. The Bayer Defendants were well aware that the frequency of peripheral

[14] *See* Linder, JA. et al. Fluoroquinolone prescribing in the United States: 1995 to 2002. *Am J Med.* 2005 Mar;118(3):259-68 ("Fluoroquinolone prescribing increased threefold in outpatient clinics and emergency departments in the United States from 1995 to 2002. Fluoroquinolones became the most commonly prescribed class of antibiotics to adults in 2002.").

neuropathy symptoms was at least on par with incidence of more minor side effects. For example, during the period from May 22, 2000 to May 31, 2002, there were 145 reports of neuropathy or neuropathy symptoms, as compared to 76 reports of headaches, 107 reports of vomiting, and 260 reports of dizziness. In addition, during the period from May 31, 2007 to May 31, 2008, the Bayer Defendants received 266 reports of neuropathy or symptoms associated with neuropathy in Avelox users. During this same time frame they received 73 reports of headaches, 151 reports of vomiting, and 265 reports of dizziness. During the period from June 1, 2010 to May 31, 2012, there were 4,295 reports of neuropathy or neuropathy symptoms, as compared to 1,358 reports of headaches, 2,344 reports of vomiting, 4,136 reports of nausea, and 4,227 reports of dizziness. Thus, for the majority of time that Avelox was sold and marketed by the Bayer Defendants, neuropathy and symptoms indicative of neuropathy remained among the frequently reported adverse effects among Avelox users.

86. Given its close association with peripheral neuropathy, the frequent occurrence of paraesthesia, hypoesthesia and other neuropathy symptoms among FLQ users posed a significant hurdle to Defendants' stated goal of expanding the use of FLQs for mild infections. If practitioners were adequately warned about the risk of serious peripheral neuropathy, they would be much more hesitant to prescribe FLQs for the type of routine infections that Defendants were targeting through their marketing strategies. So Defendants elected to conceal the true nature of the risk.

87. In order to continue to trumpet the allegedly "excellent" safety profile of FLQs, Defendants had little choice but to omit any discussion of the significant risk of paraesthesia, hypoesthesia, dysesthesia and weakness (with their implication for the risk of peripheral neuropathy), and instead focus on what would be perceived as more mild and acceptable side effects, such as headaches or nausea.

88. Beginning in at the late 1990s, Defendants aggressively marketed FLQs while at the same time concealing, through misrepresentations or omissions, the risk of peripheral neuropathy. They did this by focusing on the incidence of relatively benign side effects, such as

headaches or dizziness, while concealing the equally common but far more serious symptoms of peripheral neuropathy.

89. In a 2000 press release, the Bayer Defendants announced that Avelox exceeded two million patient uses worldwide since its international product launch in 1999. The press release went on to proclaim that spontaneous adverse event reporting from 1.58 million patient uses was low, with the most frequent reported events being nausea, vomiting and dizziness. The press release quotes Dr. Posner, Bayer Corporation's Head of Global Regulatory Affairs, as saying: "Postmarketing surveillance data are used by the FDA to assess the continued safety of approved drugs. Our study offered the opportunity to affirm that Avelox is safe and generally well-tolerated."

90. Thus, in their nationwide marketing campaigns to physicians touting Avelox's excellent safety profile, the Bayer Defendants concealed any mention of neuropathy symptoms despite disclosing more mild and less frequent side effects. The Bayer Defendants fully intended for physicians to rely on their assurances of safety and concealment of the actual safety profile when choosing to prescribe Avelox for routine infections.

91. Defendants' sales forces promoted FLQs to physicians through "details" or sales calls to physicians' offices. On these sales calls, sales representatives – often using a sales aid and/or sales script developed by Defendants' marketing teams – "detail" the physician on various uses of Defendants' products. The representations made by Defendants' sales representatives concerning Avelox were false and misleading and constituted blatant concealment of the product's actual risk profile because the Defendants were aware that CNS adverse events occurred frequently among FLQ patients.

92. Plaintiff's treating physicians would have received some form of these marketing materials, and with them the repeated misrepresentations and concealment regarding FLQs' safety profile and the concealment of the risk of irreversible peripheral neuropathy and associated symptoms.

93. Despite the claims in their marketing materials, Defendants were aware that

paraesthesia and other symptoms indicative of peripheral neuropathy had occurred frequently in FLQ patients. Defendants' marketing materials deliberately omitted any mention of neuropathy-type symptoms in their laundry list of side effects, even though the neuropathy symptoms occurred with similar, if not greater, frequency than the headaches, constipation, nausea, diarrhea, insomnia and dizziness they repeatedly mentioned.

94. Failing to disclose the high incidence of neuropathy and neuropathy-associated symptoms was not the only way in which Defendants concealed the true risk of FLQ-induced peripheral neuropathy. Defendants also misrepresented the extent of the injury. They did this in at least three ways. First, they concealed the true risk of irreversible peripheral neuropathy. Second, they concealed the fact that the irreversible peripheral neuropathy caused by FLQs is often the result of a rapid onset of symptoms – in other words, a patient could suffer permanent nerve injuries after taking as few as one or two FLQ pills. Third, Defendants misrepresented the severity of the injury and failed to disclose that it can be serious and disabling.

95. Defendants knew at least by the mid-1990s that FLQs were capable of inducing prolonged, irreversible peripheral neuropathy. This knowledge came from the numerous adverse event reports Defendants received during this period. Defendants concealed these reports from the medical community. Just a few examples of these reports are included below:

- The Bayer Defendants received an adverse event report in 2000 involving a patient who exhibited symptoms of "numbness of hands, feet and fingers (hypesthesia)"and "paresthesia" following use of Bayer's FLQ drug and who had not fully recovered from these symptoms a year later. Additional reports were received by the Bayer Defendants in 2002 of patients who experienced symptoms of "pins and needles in hands (paresthesia)" who had "not recovered" and whose symptoms were "ongoing" at time of last reporting.
- A 2005 report described a patient who was given Avelox and on the fourth day of treatment developed "pain in both legs," which was reported as "neuropathy." A month later, "pain in one leg persisted, and a drop foot developed."

96. Many of the foregoing reports highlight the rapid onset of peripheral neuropathy. In addition, numerous other early adverse event reports reviewed by Defendants provided ample indication of the rapid onset of permanent nerve damage – information not provided to the medical community. Examples include:

- An October 2000 report described a patient who developed paresthesia in his arms and legs within 24 hours of taking Avelox.
- A 2001 report noted a patient who developed neuropathy within a day of taking Avelox and the neuropathy had not resolved at the time of the report.

97. Defendants were also aware of, and concealed, the fact that, while many patients experience a rapid onset of symptoms, other patients suffered injuries after a delay in onset even though they only took the FLQ for a week or two.

98. Defendants also concealed the severity of the permanent peripheral neuropathy caused by FLQs. In numerous adverse event reports, Defendants learned of the serious and disabling nature of the irreversible peripheral neuropathy that can result from FLQ use.

99. The aforementioned internal reports and analyses underscore the extent to which Defendants were on notice that their FLQs could cause rapid onset of a permanent and severe peripheral neuropathy. But the disclosure of a permanent, disabling nerve injury that could occur after taking one or two doses of their FLQs would undercut and disrupt Defendants' marketing strategy. So instead of disclosing the risk of such an injury, Defendants chose to conceal it.

100. In order to appreciate the significance of Defendants' concealment, including both omissions and misrepresentations, regarding the extent and nature of the risk of FLQ-induced irreversible peripheral neuropathy, it is important to understand the prevailing wisdom among medical professionals regarding the nature of drug-induced peripheral neuropathy. Physicians are generally taught that the various forms of drug-induced peripheral neuropathy have two traits in common. First, they develop only after prolonged use of the offending drug, in the range of

several weeks to months.[15] Second, they are transient in nature, and resolve after the drug is discontinued.[16] While there are instances where a drug-induced neuropathy may fail to resolve and become a permanent condition, doctors are typically led to believe that this would only occur when the patient had been taking the drug for an extended period of time.

101. Thus, Defendants' failure to disclose the unique characteristics of FLQ-induced peripheral neuropathy—including rapid onset, irreversibility, and severity—meant that Plaintiff's treating physicians, when tasked with determining the cause of Plaintiff's peripheral neuropathy, would not "rule in" Avelox as a potential cause and thus Avelox use was excluded from their differential diagnosis. After all, these physicians would have assumed that the rapid onset of Plaintiff's symptoms, combined with their persistence even after discontinuation of FLQ treatment, eliminated FLQs as a possible cause. Simply put, Plaintiff's treating physicians believed that drug-induced irreversible peripheral neuropathy does not occur in these situations, and prior to August 2013, they would have had no reason to believe any differently for FLQ-induced peripheral neuropathy.

102. Defendants fraudulently concealed from physicians, patients, and the medical community that the development of peripheral neuropathy could be permanent. Defendants failed to disclose this important safety risk to patients or the medical community.

103. It was not until September 2004 that Defendants provided any kind of warning to Plaintiff or Plaintiff's physicians regarding the risk of peripheral neuropathy. It was at this point in time that Defendants warned that "rare" cases of "polyneuropathy . . . resulting in

---

[15] *See, e.g.*, Ropper A. et al., Principles of Neurology – Tenth Edition, p. 1336, McGraw-Hill Education (2014) (most drug-induced neuropathies occur "after large cumulative doses of the drug have been given (e.g., in cancer chemotherapy) or after prolonged administration"); Benichou C., Adverse Drug Reactions: A Practical Guide to Diagnosis and Management, pp. 105-109, J. Wiley & Sons (1994) ("Most drug-induced polyneuropathies are subacute having an onset of a few weeks or months.").

[16] *See* Vilholm O.J. et al. Drug-Induced Peripheral Neuropathy. *Basic & Clinical Pharmacology & Toxicology* 2014 Aug; 115(2):185-192 ("Drug-induced peripheral neuropathy can begin weeks to months after initiation of treatment with a particular drug and reach a peak at, or after, the end of treatment. In most cases, the pain and paraesthesia completely resolve after cessation of treatment.").

paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones." This warning failed to disclose the true risk of irreversible peripheral neuropathy, the possibility of rapid onset, or the serious and disabling nature of the injury. By underscoring the "rare" incidence of neuropathy among FLQ users, Defendants reinforced the misleading statements in their marketing materials that the most frequent symptoms were minor reactions such as headaches and diarrhea.

104. Defendants had a duty to disclose all facts about the risks associated with use of the medication. However, Defendants failed to disclose in their FLQ labels that the onset of peripheral neuropathy is often rapid or that neuropathy symptoms were among the most common side effects (and certainly were not rare).

105. Further, upon information and belief, Defendants intentionally misrepresented the number of reported cases of peripheral neuropathies by improperly excluding certain forms of peripheral neuropathy from the total number of cases counted towards the condition. In this way they concealed the true risk profile of their product. This allowed Defendants to falsely represent to the medical community and patients in the labeling that reported cases of peripheral neuropathy were "rare," thereby vastly minimizing the risk.

106. The Bayer Defendants adopted procedures to conceal the extent and nature of the risk of irreversible neuropathy. For example, when reporting on the incidence of Avelox-induced peripheral neuropathy in 2009, the Bayer Defendants intentionally excluded all cases that exhibited a rapid onset of symptoms. In defense of this decision, the Bayer Defendants cited a leading textbook which stated that drug-induced peripheral neuropathies have an onset "of a few weeks or months." The problem, of course, was that the Bayer Defendants knew long before 2009 that, in the case of FLQ-induced neuropathy, the time to symptom onset is very rapid, including after a single dose. Yet the Bayer Defendants never disclosed this knowledge to the medical community. Thus, by excluding cases of rapid onset, the Bayer Defendants knew they would avoid having to report the majority of Avelox- and Cipro-induced peripheral neuropathies. As they wrote in their 2009 report: "In the majority of reports the treatment

duration is well shorter than 8 days, in many reports the onset is within hours after a single dose. . . . Thus, applying the definitions as stated in the method-section, no cases of (poly-)neuropathy could be identified, and the association of the reported clinical symptoms with moxifloxacin was either excluded or unlikely in the final evaluation." The low incidence of FLQ-associated irreversible peripheral neuropathy therefore became a self-fulfilling prophecy, since Defendants' criteria for such an association excluded the very characteristic (rapid onset) that is a hallmark of the association.

107. Defendants, have publicly recognized that FLQs should not be used as a first-line treatment for uncomplicated or minor infections, such as acute maxillary sinusitis, acute exacerbation of chronic bronchitis, and uncomplicated urinary tract infections. The senior director of global clinical development at Bayer Healthcare recently testified before the FDA that "Quinolones are definitely an alternative, but no one is recommending them as a first line [treatment] for the uncomplicated cases."[17] Contrary to this representation, Defendants marketed and promoted FLQs for more than a decade to physicians, hospitals, and the medical community as a first-line treatment for uncomplicated infections, including sinusitis, bronchitis, and urinary tract infections. All the while, Defendants concealed from the medical community that opinion leaders, including its own personnel, acknowledged that the product was inappropriate for such use.

108. Defendants were obligated under federal regulations to revise the labeling as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved. 21 C.F.R. 201.57(e). Despite the information known to Defendants discussed above, Defendants deliberately failed to update their FLQ labels to reflect the rapid onset of symptoms or the risk of developing *permanent* peripheral neuropathy or the severity of nerve damage or the higher incidence of neuropathy symptoms. Defendants knew, prior to Plaintiff's use of Avelox, that central nervous system-related effects were one of the

[17] Testimony at the FDA Subcommittee Advisory Hearing, Nov. 5, 2015.

most common adverse effects of quinolones and that the onset of events like peripheral neuropathy could be rapid and irreversible. Despite this information, Defendants deliberately failed to update their Avelox label, marketing materials, or educational and promotional documents and statements to reflect this important safety information or to modify their marketing materials and mantras.

109. In failing to update their labels and marketing materials, Defendants intended that that the misinformation contained in the label would be relied upon by Plaintiff and Plaintiff's prescribing physicians, which it was. As a direct result of Plaintiff's and Plaintiff's prescribing physician's reliance on the false information contained within the Avelox label, Plaintiff was prescribed and took Avelox and developed permanent peripheral neuropathy.

110. The nature of Plaintiff's injuries and the relationship of such injuries to FLQs were inherently undiscoverable prior to the full dissemination of the FDA disclosure of risk information that began in August 2013.

111. Accordingly, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through reasonable care and diligence should have known, of their claims against Defendants, and in any event such tolling should continue until at least the date of FDA's disclosure of risk information in August 2013.

112. Plaintiff did not discover, and through the exercise of reasonable care and due diligence should not and could not have discovered, Plaintiff's illnesses and injuries or their relationship to the FLQ drugs until after August 2013. Plaintiff's suit is filed well within the applicable statute of limitations period under appropriate application of their state's "discovery rule."

113. In the alternative, the facts of Plaintiff's claims made it impossible for Plaintiff to discover the true nature of the injuries and/or causes of action within the applicable limitations period. In particular, Defendants' misrepresentations and omissions that constituted active concealment regarding the true nature of the risks associated with their FLQ drugs prevented Plaintiff from discovering the wrongful acts on which the causes of action are based. Prior to

August 15, 2013, Plaintiff's treating physicians denied, ignored or were unaware of any possibility that Plaintiff's injuries were causally associated with FLQs. This was the result of Defendants' omissions from and misrepresentations to the medical community and to the general public. Plaintiff did not discover the association between the use of FLQs and peripheral neuropathy until around January 2016 from television. Thus, while Plaintiff acted diligently to determine both the nature and the cause of the injuries, Plaintiff's efforts were thwarted by Defendants' fraudulent concealment. Plaintiff filed this lawsuit within the applicable limitations period of the date Plaintiff knew or through the exercise of reasonable care and due diligence should have known of the claim.

114. Unlike ordinary consumers of prescription drug products, prescription drug manufacturers are held to the standard of experts on their products. And unlike ordinary consumers, prescription drug manufacturers are obligated to keep abreast of scientific knowledge, discoveries, advances and research in the field related to their products, and are presumed to know what is imparted thereby. Conversely, ordinary consumers (like Plaintiff) is not presumed, as are drug manufacturers, to have superior or continuing knowledge of medical and scientific evidence concerning the drugs they take, particularly with respect to drugs they have previously ingested. Plaintiff, as an ordinary consumer, had no reason to suspect that their use of Defendants' FLQs might have caused or contributed to the development of permanent peripheral neuropathy until after August 2013 at the earliest because of Defendants' fraudulent concealment of the risk as noted above. In addition, physical symptoms alone, without knowing or being able to discern the cause, is insufficient to start the statute of limitations clock running.

115. Plaintiff could not have reasonably discovered the full extent of the injuries and their relationship to the FLQ drugs until some time after August 2013. It was only then that the FDA disclosed on its website that there was a risk of developing *irreversible* peripheral neuropathy with FLQ use. Moreover, the seriousness of developing peripheral neuropathy was not highlighted in the media or in any FLQ label until the black box warning was added for

peripheral neuropathy in May 2016. Before then, the relationship was not reasonably knowable by Plaintiff.

116. The lack of awareness concerning the causal relationship between FLQs and irreversible peripheral neuropathy was not the result of silence or passive concealment. Defendants, through their marketing statements and labeling, made affirmative representations and engaged in deliberate omissions to the medical community and patients, both of which suggested, both expressly and impliedly, that symptoms of neuropathy were reversible, thereby excluding suspicion of any drug-induced relationship or cause and preventing subsequent discovery.

117. The mere publication of the risk information on the FDA's website in August 2013 did not provide the general public or the medical community with information sufficient to arouse suspicion of a relationship between FLQ use and permanent peripheral neuropathy. There was no widespread media coverage, and Defendants failed to provide any additional substantive disclosure to the general public about the label change or risk information, whether in the form of website communication, newspaper or television advertisements. Plaintiff's duty to investigate does not begin to run until Plaintiff actually had a reason to investigate. Defendants' affirmative representations in their FLQ labels prior to August 2013 foreclosed any such duty or suspicion because, according to the labeling, FLQ-induced neuropathies were reversible once the drug was discontinued. Accordingly, it was only well after August 2013 that Plaintiff may be said to have had a reason to investigate the cause of Plaintiff's permanent peripheral neuropathy. In the alternative, a diligent investigation would not have uncovered FLQ use as the cause of Plaintiff's injuries, for the reasons expressed above.

118. Even in the absence of the application of a "discovery rule," Plaintiff has timely filed the claims from the date of injury. Plaintiff further avers that before addressing when an injury arises for statute of limitations purposes, it is necessary to first identify the actionable injury. Once the actionable injury is identified, the determination will have to be made as to when it occurred and the party asserting the limitations bar bears the burden of proving this

within a reasonable degree of medical certainty, which will be a case-by-case determination.

119. As a result of Defendants' actions, Plaintiff and Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

120. Therefore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality, and nature of Avelox. Defendants were under a duty to disclose the true character, quality, and nature of Avelox because this was non-public information over which Defendants had and continue to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

121. Further, Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein, and because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

122. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent conduct, as described in the preceding paragraphs. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians and healthcare providers the true and significant risks associated with Avelox use.

123. As a result of Defendants' fraudulent actions, Plaintiff and Plaintiff's prescribing physicians and healthcare providers were unaware and could not have reasonably known or learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations. Plaintiff has been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on Plaintiff's part. Defendants actively concealed from Plaintiff and/or Plaintiff's physicians the true risks associated with the use of

Avelox. Defendants' acts and omissions included failing to disclose the truth about the safety and efficacy of Avelox to Plaintiff's physicians and/or Plaintiff, and concealing through misrepresentation the safety and efficacy of Avelox. Plaintiff and Plaintiff's physicians reasonably relied on Defendants to disseminate truthful and accurate safety and efficacy information about their drugs and warn of the side effects complained of herein.

124. Although some aspect of the injury may have been known to Plaintiff and Plaintiff's physicians, due to Defendants' intentional concealment, an essential fact to bring thier cause of action was unknown. Plaintiff, lacking the reasonable means to discover vital information, reasonably relied on the concealment of essential facts that Defendants, having actual knowledge of material facts, actively and deliberately concealed with the intent to prevent discovery thereof by others, including the Plaintiff. As a consequence of Defendants' conduct, Plaintiff was without knowledge of those facts and without means to discover them within the period of the statute of limitations, thereby relying to their detriment on Defendants' conduct.

125. As such, the running of any statute of limitations has been tolled by reason of Defendants' affirmative misrepresentations and omissions.

126. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the defective nature of FLQs. Defendants, at all times relevant hereto, were under a duty to disclose the true character, quality and nature of Avelox because this was non-public information over which the Defendants had and continue to have exclusive control, and because Defendants knew this information was not available to the Plaintiff or Plaintiff's physicians. In addition, Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

127. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, often as a front-line therapy for minor infections, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to

determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the discovery rule, the doctrine of fraudulent concealment and/or the doctrine of equitable estoppel from relying upon any statute of limitations.

128. Had Plaintiff's physicians known of the true risk profile of Defendants' products, the physicians would not have prescribed the products to Plaintiff. Had Plaintiff's physicians known of the true risk profile of Defendants' products, the physicians would have transferred this information to Plaintiff. Had Plaintiff known of the true risk profile of Defendants' products, Plaintiff would have declined to use those products. The physicians would have honored Plaintiff's wishes by failing to prescribe the product.

129. Neither Plaintiff nor Plaintiff's physicians were aware of the true risk profile of Defendants' products before Plaintiff was injured. Plaintiff learned that Defendants' products might be responsible for their injuries within the proscriptive periods prescribed by the state law governing Plaintiff's claims.

130. For each Count hereinafter alleged and averred, the above and following Paragraphs should be considered re-alleged as if fully rewritten.

COUNT I

[Strict Liability]

131. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

132. The FLQ drugs manufactured, marketed, supplied and/or distributed by Defendants were defective at the time of manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying such labels failed to warn of the dangerous risks they posed, including the risk of developing irreversible peripheral neuropathy.

133. At all times alleged herein, the FLQs manufactured, marketed, supplied, and/or distributed by Defendants were defective, and Defendants knew that their FLQ drugs were to be used by consumers without inspection for defects. Moreover, Plaintiff, Plaintiff's prescribing

physicians, and Plaintiff's healthcare providers neither knew nor had reason to know at the time of Plaintiff's use of the drugs of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

134. At all times alleged herein, the Defendants' FLQs were prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

135. The design of Defendants' FLQ drugs were defective in that the risks associated with using the drugs as a first-line therapy for infections that did not dictate the use of an FLQ outweighed any benefits of their design. Any benefits associated with the use of the FLQs in such situations were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing irreversible peripheral neuropathy.

136. The defect in design existed when the product left Defendants' possession.

137. At the time FLQs left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting their drug.

138. As a result of the defective condition of Defendants' FLQs, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT II

[Product Liability – Failure to Warn]

139. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

140. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting their FLQ drugs and, through that conduct, have knowingly and intentionally placed such drugs into the stream of commerce with full knowledge that their products reach consumers such as Plaintiff who ingested them.

141. Defendants did in fact sell, distribute, supply, manufacture, and/or promote their FLQ drugs to Plaintiff and to Plaintiff's prescribing physicians. Additionally, Defendants expected the drugs they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and they did in fact reach – prescribing physicians and consumers, including Plaintiff and Plaintiff's prescribing physicians, without any substantial change in the condition from when they were initially distributed by Defendants.

142. At all times herein mentioned, Defendants' FLQ drugs were defective and unsafe in manufacture such that they was unreasonably dangerous to the user, and were so at the time they were distributed by Defendants and ingested by Plaintiff. The defective condition of such drugs was due in part to the fact that they were not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of their use.

143. This defect caused serious injuries to Plaintiff, who used Defendants' FLQs in their intended and foreseeable manner.

144. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that their products did not cause users to suffer from unreasonable and dangerous side effects.

145. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid products that they were dangerous and unsafe for the use and purpose for which they were intended.

146. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with their FLQ products, namely irreversible peripheral neuropathy.

147. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that their FLQ drugs caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from their use, even though this side effect was

known or reasonably scientifically knowable at the time of their initial marketing and distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

148. Plaintiff could not have discovered any defect in the subject products through the exercise of reasonable care.

149. Defendants, as the manufacturers and/or distributors of the FLQ products, are held to the level of knowledge of experts in the field.

150. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

151. Had Defendants properly disclosed the risks associated with their FLQ drugs, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using the drugs.

152. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT III

[Negligence]

153. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

154. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of the FLQ drugs.

155. Defendants breached their duty of reasonable care to Plaintiff in that they

negligently promoted, marketed, distributed, and/or labeled the drugs.

156. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Defendants' FLQ drugs;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of the dangerous and defective characteristics of Defendants' FLQ drugs;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for Defendants' FLQ drugs;

d) In promoting Defendants' FLQ drugs in an overly aggressive, deceitful, and fraudulent manner, including as a first-line therapy to treat infections for which they were not required despite evidence as to the drug's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;

e) In representing that Defendants' FLQ drugs were safe for their intended use when, in fact, the products were unsafe for their intended use;

f) In failing to perform appropriate pre-market testing of Defendants' FLQ drugs;

g) In failing to perform appropriate post-market surveillance of Defendants' FLQ drugs;

h) In failing to adequately and properly test Defendants' FLQ drugs before and after placing them on the market;

i) In failing to conduct sufficient testing on Defendants' FLQ drugs which,

if properly performed, would have shown that it had the serious side effect of causing irreversible peripheral neuropathy;

j) In failing to adequately warn Plaintiff and Plaintiff's healthcare providers that the use of Defendants' FLQ drugs carried a risk of developing irreversible peripheral neuropathy;

k) In failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of their FLQ drugs; and

l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from FLQ ingestion as described herein.

157. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

158. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, physical impairment, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IV

[Breach of Express Warranty]

159. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

160. Before Plaintiff was first prescribed Defendants' FLQ drugs and during the period in which Plaintiff used the drugs, Defendants expressly warranted that their FLQ drugs were safe.

161. Defendants' FLQs did not conform to these express representations because their drugs were not safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.

162. As a direct and proximate result of this wrongful conduct, Plaintiff was injured as described above.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT V

[Breach of Implied Warranty]

163. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

164. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold FLQ drugs (including Avelox), and before such drugs were prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that these drugs were of merchantable quality and safe and fit for the use for which they were intended.

165. Plaintiff, individually and through Plaintiff's prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

166. Plaintiff was prescribed, purchased, and used the subject products for their intended purpose.

167. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject products until after Platintiff used them.

168. Contrary to the implied warranty for the subject products, Defendants' FLQs are

not of merchantable quality, and they were neither safe nor fit for their intended uses and purposes, as alleged herein.

169. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VI

[Fraud]

170. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

171. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their FLQ drugs, owed a duty to provide accurate and complete information regarding these drugs.

172. Defendants' advertising, marketing and educational programs, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of FLQ drugs were safe for human use, had no unacceptable side effects, and would not interfere with daily life.

173. Defendants did not properly study nor report accurately the results of their studies in terms of risks and benefits of their FLQ drugs. For instance, Defendants failed to investigate or initiate any studies or testing following the safety signal generated by Karlman, et al. in 1988, wherein the study determined that an adverse event of peripheral paresthesia was "probably related" to ciprofloxacin treatment.

174. Defendants purposefully concealed, failed to disclose, misstated, downplayed, and

understated the health hazards and risks associated with the use of their FLQs. For instance, the Bayer Defendants actively engaged in fraudulently and intentionally polluted the scientific literature related to safety and efficacy of their FLQ drugs. The Bayer Defendants did this primarily through selected Bayer physicians and other paid medical consultants and Key Opinion Leaders ("KOLs")—including Peter Ball, Glenn Tillotson,[18] Lionel Mandell, B A. Lipsky, H. Lode, Ralf Stahlmann, and Robert Owens—who regularly touted benefits of these drugs while concealing, misstating, and downplaying the known adverse and serious health effects.[19] A sample of such statements include:

> "The most common adverse effects of the fluoroquinolones involve the gastrointestinal tract, skin and CNS, and are mainly mild and reversible." Ball, P., Mandell, L., Niki, Y., Tillotson, G. Comparative tolerability of the newer fluoroquinolone antibacterials. *Drug Saf.* 1999;21:407–421.
>
> "Ciprofloxacin is well tolerated; the incidence of adverse events is low and serious adverse events are rare." Ball, P. Safety of the new fluoroquinolones compared with ciprofloxacin. *J Chemother*. 2000;12:8–11.
>
> "A review of 37 published clinical trials in more than 3,500 patients, as well as data obtained from Bayer Corporation, revealed that ciprofloxacin performed as well as or better than the standard comparison drugs. . . . The clinical efficacy of these [FLQ] compounds has largely been demonstrated to be equivalent to that of commonly prescribed agents." Ball, P., Chodosh, S., Grossman, R., Tillotson, G., Wilson, R. Causes, Epidemiology, and Treatment of Bronchial Infections, Infect Med. 2000; 17(3).
>
> "The fluoroquinolone group has made a major contribution to the care of infected patients for over 15 years. Recent problems with idiosyncratic, unexpected and serious adverse reactions have affected very small numbers of patients and, whilst

---

[18] In 2000, Glenn Tillotson was the director of international scientific relations at Bayer Corporation and co-developer of Cipro and Avelox. According to one of his online biographies: "After training in medical microbiology and infectious diseases in the United Kingdom he subsequently spent 13 years at Bayer AG in the UK, US and Germany where he was instrumental in the development of ciprofloxacin and moxifloxacin as well as other drugs in the Bayer AG portfolio." *See* http://antibiotics.omicsgroup.com/ocm/2015/glenn-s-tillotson-senior-scientific-advisor-of-optimer-pharmaceuticals-inc-usa.

[19] *See, e.g.*, Tillotson, G.S., Rybak, J. New milestones achieved in fluoroquinolone safety. *Pharmacotherapy*. 2001;21:358–360; Tillotson, G.S., Ball, P. Fluoroquinolone safety profiles—a review. in: *Today's Therapeutic Trends*. 1. 3rd ed. Communications Media for Education Inc; 2003:419–435.

> leading to the loss of the individual agents concerned, should not raise concerns about the class as a whole without scientific foundation. . . . After treatment of almost 20 million patients with these newer agents, its window of opportunity appears unlikely to be cut short by untimely reports of significant adverse reactions." Ball, P. Adverse drug reactions: implications for the development of fluoroquinolones. *Journal of Antimicrobial Chemotherapy* (2003) 51, *Suppl. S1*, 21–27.

175. In fact, when the first major epidemiological study suggesting the permanency of peripheral neuropathy associated with FLQ use was published by Cohen (2001) in the *Annals of Pharmacotherapy*, Glenn Tillotson quickly sought to downplay the significance of Cohen's findings.[20] It is not coincidental that the publication dates of the industry-driven articles cited above correspond to the timeframe when FLQs became the most commonly prescribed class of antibiotics to adults in the United States.[21]

176. Thus, Defendants, through the publication of medical literature, deceived potential users and prescribers of FLQ drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects, including permanent peripheral neuropathy.

177. Defendants similarly used promotional practices to deceive potential users and prescribers of FLQ drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects, including permanent peripheral neuropathy.

178. Defendants also falsely and deceptively kept relevant information from potential FLQ users and minimized prescriber concerns regarding the safety and efficacy of FLQs. For instance, despite learning as early as 1988 (Karlman, et al.) that there was reasonable evidence of an association of a serious hazard with their FLQs, Defendants intentionally withheld this

---

[20] Tillotson GS. Comment: peripheral neuropathy syndrome and fluoroquinolones. *Ann Pharmacother*. 2001 Dec;35(12):1673-4.

[21] *See* Linder, JA. et al., Fluoroquinolone prescribing in the United States: 1995 to 2002. *Am J Med.* 2005 Mar;118(3):259-68 ("Fluoroquinolone prescribing increased threefold in outpatient clinics and emergency departments in the United States from 1995 to 2002. Fluoroquinolones became the most commonly prescribed class of antibiotics to adults in 2002.").

information from physicians and patients until September 2004, when the FLQ labeling was finally changed to reflect any risk of developing neuropathy. Even then, however, Defendants sought to minimize the frequency and permanency of these serious events by indicating that they were "rare." Defendants knew these labeling statements were false and misleading, because they knew as early as the 1990s that central nervous system-related effects were more common with quinolones than with other antimicrobial classes of drugs and that the onset of events like peripheral neuropathy could be rapid and irreversible. Defendants continued, through August 2013, to misrepresent in their product labels that cases of neuropathy were "rare."

179. Defendants also continued, from August 2012 through August 2013, to intentionally misrepresent that irreversible neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms. More specifically, until the August 2013 label change, from August 2012 through August 2013, the Avelox label specifically stated that the drugs should be "discontinued if the patient experiences symptoms of neuropathy . . . in order to prevent the development of an irreversible condition." This statement is misleading because it implies that permanent peripheral neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms, which, as noted above, is false. This type of misrepresentation continued to misinform patients and physicians that the use of FLQs could not be the cause of permanent peripheral neuropathy.

180. The scientific and medical communities were misled as to the true nature of the risk and benefits of the Defendants' FLQ drugs in particular and in general as to the treatment needs and options for patients in need of antibiotic therapy. It was not until the FLQ label change in August 2013 regarding the rapid onset and potentially permanent nature of neuropathies that the truth began to be generally available in the scientific community. Even then, however, physicians had been so conditioned by the false science published and/or funded for years by Defendants that it was difficult for many of those physicians to accept the truth about the risks and lack of benefits associated with these FLQ drugs. This realization, that FLQ

drugs have for years been overprescribed, which is supported by independent studies,[22] has once again prompted the FDA to take action. In November 2015, a FDA subcommittee advisory panel was convened wherein panel members noted that FLQ drugs are overprescribed for common infections when other treatments would work as well with less risk. The advisory panel called on the FDA to strengthen labeling warnings and clarify when FLQ drugs should—and should not—be used. Then, on May 12, 2016, the FDA issued a safety announcement advising that "the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options." The FDA instructed that patients with these conditions should not be treated with a fluoroquinolone if alternative treatment options are available. The May 12th announcement also cautioned that a safety review demonstrated that FLQs "are associated with disabling and potentially permanent serious side effects that can occur together." The side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

181. The misconceptions as to the true risks and benefits of Defendants' FLQ drugs were pervasive throughout the medical and scientific communities due to the marketing methods employed by Defendants that included the following:

(a) The publication of fraudulent scientific papers in scientific and medical literature;

(b) Providing false and misleading information to doctors during sales and detailing calls at the doctors' offices or at medical or scientific conferences and meetings;

(c) Funding and sponsoring physicians, consultants and/or Key Opinion Leaders to disseminate false and misleading scientific and medical information through medical journals and publications;

---

[22] *See* Lautenbach E, Larosa LA, Kasbekar N, Peng HP, Maniglia RJ, Fishman NO. Fluoroquinolone utilization in the emergency departments of academic medical centers: prevalence of risk factors for inappropriate use. *Arch Intern Med*. 2003;163(5):601–605.

(d) Funding third-party companies to disseminate false and misleading scientific and medical information through its publications and its members to physicians and patients;

(e) Funding continuing medical education to disseminate false and misleading information to doctors;

(f) Paying specialists in the field to meet with prescribing doctors for the purpose of disseminating false and misleading information about the risks and benefits of the FLQ drugs;

(g) Disseminating direct to consumers advertising to drive patients to their doctors' offices to ask for their FLQ drugs based on false and misleading information regarding the risks and benefits of the drugs.

182. In particular, Defendants falsely and deceptively misrepresented material facts regarding the safety and effectiveness of FLQ drugs and fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of their products, including by concealing the following information:

(a) That there was evidence of peripheral paraesthesia associated with FLQ therapy as early as 1988;

(b) That there was evidence demonstrating that FLQs increase the risk of irreversible peripheral neuropathy as early as 1996;

(c) That the J&J Defendants in particular knew in the mid-1990s that cases of paraesthesia were one of the three "most frequently reported AEs" related to the central nervous system.

(d) That the FLQ drugs were not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy;

(e) The severity, frequency, rapid onset, and potentially disabling nature of peripheral neuropathy caused by the FLQ drugs;

(f) The wide range of injuries caused by FLQ drugs to multiple body systems (e.g., musculoskeletal, neuropsychiatric, peripheral nervous system, senses like vision or hearing, skin, and cardiovascular); and

(g) That FLQs should not be used as a first-line therapy to treat infections for which they are not required.

183. The misrepresentations and/or active concealments were perpetuated directly and/or indirectly by Defendants. Moreover, as a result of these efforts it was accepted by the medical and scientific communities that these FLQ drugs had a certain risk benefit profile that was shown to be completely false by independent studies, case series, and individual AE reports (including those contained in the FDA AERS).

184. Defendants were in possession of evidence demonstrating that the FLQ drugs caused serious and sometimes debilitating side effects, including permanent peripheral neuropathies. Nevertheless, Defendants continued to market such products by providing false and misleading information with regard to its safety and efficacy to Plaintiff and Plaintiff's treating physicians.

185. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry generally.

186. Defendants made these false representations with the intent or purpose that Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry would rely on them, leading to the widespread use of FLQs by Plaintiff as well as the general public.

187. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of these facts, Plaintiff's physicians would not have prescribed and Plaintiff would not have taken Avelox.

188. Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and

relied on the absence of information regarding the dangers of FLQs that Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of FLQs. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

189. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested the Defendants' FLQ drugs and suffered injuries as set forth herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VII

[Negligent Misrepresentation]

190. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

191. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry the safety and effectiveness of FLQs and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by FLQ drugs.

192. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that FLQs had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

(a) That there was evidence (e.g., Karlman, et al.) of peripheral paraesthesia associated with FLQ therapy (ciprofloxacin) as early as 1988;

(b) That there was evidence (e.g., Hedenmalm, et al.) demonstrating that FLQs increase the risk of irreversible peripheral neuropathy as early as 1996;

(c) That the FLQ drugs were not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy;

(d) The severity, frequency, rapid onset, and potentially disabling nature of peripheral neuropathy caused by the FLQ drugs;

(e) The wide range of injuries caused by FLQ drugs to multiple body systems (e.g., musculoskeletal, neuropsychiatric, peripheral nervous system, senses like vision or hearing, skin, and cardiovascular); and

(f) That FLQs should not be used as a first-line therapy for minor or uncomplicated infections.

193. The negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

194. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry.

195. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry would rely on them, leading to the use of FLQs by Plaintiff as well as the general public.

196. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had Plaintiff been aware of said facts, Plaintiff's physicians would not have prescribed and Plaintiff would not have taken Avelox.

197. Plaintiff justifiably relied on and/or were induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Defendants' FLQ drugs and relied on the absence of information regarding the dangers of these drugs which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

198. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with their FLQ drugs in a timely manner.

199. Defendants made the representations and actively concealed information about the defects and dangers of their FLQ drugs with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting these FLQs as a treatment.

200. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Plaintiff ingested Defendants' FLQ drugs and suffered injuries as set forth herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII

[Fraudulent Concealment]

201. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

202. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed their wrongful conduct from the Plaintiff with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on such material representations. First, Defendants had actual knowledge of the defective and dangerous nature of the FLQ drugs. Second, Defendants failed to conduct adequate testing on their FLQ drugs to establish safety and efficacy. Third, Defendants had actual knowledge of their misrepresentations, negligence, breach

of warranties, and false, misleading, deceptive, and unconscionable conduct. Yet, Defendants continued to perpetuate their wrongful conduct with the intent and fixed purpose of concealing their wrongs from the Plaintiff and the public at large.

203. Plaintiff and Plaintiff's prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiff was injured as a direct and proximate result.

204. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, Plaintiff's prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on Defendants' misrepresentations. Plaintiff and Plaintiff's prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiff was injured as a result.

205. Defendants, as the manufacturer and/or distributor of their FLQ drugs, were in a position of superior knowledge and judgment regarding any potential risks associated with their drugs.

206. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the FLQ drugs at issue in this lawsuit, said breach or breaches constituting fraud because of its propensity to deceive others or constitute an injury to public interests or public policy.

207. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of FLQ drugs to increase sales of the drugs at the expense of informing Plaintiff that, by ingesting these drugs, Plaintiff was at a significantly-increased risk of developing irreversible peripheral neuropathy and/or injuries to multiple other body systems (e.g., musculoskeletal, neuropsychiatric, senses like vision or hearing, skin, and cardiovascular).

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IX

[Violation of Consumer Protection Laws/Consumer Fraud Laws]

208. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

209. Plaintiff pleads this Count in the broadest sense available under state law, to include pleading same pursuant to all substantive law that applies to this case, regardless of whether arising under statute and/or common law.

210. Plaintiff used Defendants' FLQ drugs and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

211. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

212. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of their FLQ drugs.

213. Defendants violated consumer protection laws of this state.

214. Defendants uniformly communicated the purported benefits of their FLQ drugs while failing to disclose the serious and dangerous side effects related to the use of FLQs and of the true state of FLQs' safety, efficacy, and usefulness. Defendants made these representations to

physicians, the medical community at large, and to patients and consumers, such as Plaintiff, in the marketing and advertising campaign described herein.

215. Defendants' conduct in connection with their FLQ drugs were also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of FLQs.

216. As a result of these violations of consumer protection laws, Plaintiff has incurred and will incur serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

PUNITIVE DAMAGES

217. At all times material hereto, Defendants knew or should have known that their FLQ drugs were inherently dangerous with respect to the risk of irreversible peripheral neuropathy.

218. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their FLQ drugs.

219. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the FLQ drugs.

220. At all times material hereto, Defendants knew and recklessly disregarded the fact that their FLQ drugs cause the chronic disease of irreversible peripheral neuropathy and/or injuries to multiple other body systems.

221. Notwithstanding the foregoing, Defendants continued to aggressively market their FLQ drugs to consumers, including Plaintiff herein, without disclosing the aforesaid side effect.

222. Defendants knew of their FLQ drug's lack of warnings regarding the risk of developing irreversible peripheral neuropathy and/or injuries to multiple other body systems, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell their FLQ drugs without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by their FLQ drugs.

223. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable Plaintiff to weigh the true risks of using FLQs against their benefits.

224. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff as endured pain and suffering, have suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are prolonged and/or permanent and will continue into the future.

225. Defendants' aforesaid conduct was committed with knowing, conscious, careless,

reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

RELIEF REQUESTED

WHEREFORE, Plaintiffs pray for relief and judgment against Defendants as follows:

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for Defendants' FLQ drugs;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) For such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

DATED: 5/5/17

AYLSTOCK, WITKIN, KREIS & OVERHOTLZ, PLLC

Respectfully submitted,

By: _____

James Barger (PA #310056)
Aylstock, Witkin, Kreis & Overholtz, PLLC
17 East Main Street, Suite 200
Pensacola, FL 32502
Phone: 850-202-1010
Facsimile: 850-916-7449
jbarger@awkolaw.com

Attorney for Plaintiff